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VIII. SAFETY AND EFFECTIVENESS SUMMARY

The ASSERACHROM® HPIA test kit is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of anti-heparin-platelet factor 4 (anti-heparin-PF4) antibodies generated during Type II heparin-induced thrombocytopenia (Type II HIT). The reagent system can be used to test human citrated plasma or serum samples.

The patient sample suspected to contain antibodies to heparin-PF4 complexes is allowed to incubate in a plastic microwell that has been precoated with heparin-PF4 complexes (Reagent ①). If any heparin-PF4 antibodies are present, they are captured by the heparin-PF4 complexes. Next, goat anti-human-IgG/IgA/IgM antibodies coupled with peroxidase (Reagent ②) is added, and this binds to the available antigenic determinants of the heparin-PF4 antibodies that are immobilized in the first step, forming the "sandwich". The bound enzyme peroxidase is then revealed by its activity in a predetermined time on the substrate ortho-phenylenediamine in the presence of hydrogen peroxide (Reagents ③a + ③b). After stopping the enzymatic reaction with a strong acid, the intensity of the color produced is related to the heparin-PF4 antibody level initially present in the patient sample. (This test procedure has been granted U.S. Patent No. 5,466,582, issued in 1995.)

The kit provides sufficient reagents to perform 48 tests in micro-ELISA plate format. Reagents in intact (unopened) kits remain stable for 24 months after their date of manufacture, when stored at 2°-8°C. Reconstituted reagent stabilities are as follows: Reagent ① (microwell strip precoated with heparin-PF4 complexes) must be used immediately after opening of its package; Reagent ② (anti-human-IgG/IgA/IgM-Peroxidase), 24 hours at 2°-8°C; Reagent ③a (ortho-Phenylenediamine) dissolved together with Reagent ③b (Urea Peroxide), 1 hour at room temperature (18°-25°C); ready-for-use Reagent ④ (Dilution Buffer), 1 month at 2°-8°C, when free of contamination; 1:20 diluted Reagent ⑤ (Washing Solution), 15 days at 2°-8°C, when free of contamination; Reagent ⑥ (HPIA Reference) and both the Reagents ⑦a and ⑦b (Controls [1] and [2], respectively), 4 hours at 20°C and 1 month frozen at –20°C.

Test results for unknown patient samples observed with the ASSERACHROM® HPIA reagent system are interpreted by comparing their absorbance values with that of the HPIA Reference (Reagent ⑥), and confirmed with those of the negative and positive controls (Reagents ⑦a and ⑦b, respectively). Any unknown sample that gives an absorbance value greater than x% of that of the HPIA Reference is considered positive. The value of x is indicated in the Assay Value insert provided with the kit for each lot.

A parallel evaluation of ASSERACHROM® HPIA in testing of 19 normal samples and 49 patient samples with a variety of pathologies has demonstrated that the proposed reagent system is substantially equivalent to the predicate device GTI-PF4 ELISA that has been cleared by FDA under K983379.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 12 2001

Andrew Loc B. Le, Ph.D.
Director of Regulatory Affairs
and Quality Assurance
Diagnostics Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Re: K003767
Trade Name: ASSERACHROM® HPIA Test Kit
Regulatory Class: II
Product Code: LCO
Dated: December 6, 2000
Received: December 6, 2000

Dear Dr. Le:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

510(k) Number (if known): K003767

Device Name: ASSERACHROM® HPIA Test Kit

Indications for Use:

The ASSERACHROM® HPIA test kit is intended for use as a qualitative procedure for the detection of anti-heparin-platelet factor 4 (anti-Heparin-PF4) antibodies in citrated plasma or serum by the sandwich technique of enzyme-linked immunosorbent assay (ELISA).

The presence in plasma or serum of anti-Heparin-PF4 antibodies, together with a concurrent drop in platelet count, is generally associated with Type II heparin-induced thrombocytopenia (Type II HIT), a condition that occurs during heparin therapy, leading to arterial or venous thrombosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003767

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)